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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,956	10/01/2003	Suzanne Zebedee	323-100US D	9260

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/677,956	ZEBEDEE ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *127-147* is/are pending in the application.

4a) Of the above claim(s) *127, 128, 132-36, 145* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *124-126,129-131,137-144,146 and 147* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3-21-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 124-147 are pending in the application.

2. In the prior action, mailed on December 12, 2006, claims 112-123 were pending in the application, with claims 112-114 under consideration and rejected, and claims 116-118 objected to, and claims 115 and 119-123 were withdrawn from consideration.

3. In the Response of January 11, 2007, claims 112-123 were cancelled and new claims 124-136 were added. Additional claims 137-147 were added in the supplemental response of January 31, 2007.

4. Of the currently pending claims, claims 127, 128, 132-136, and 145 correspond to previously withdrawn inventions, and are thus withdrawn from consideration.

5. Claims 124-126, 129-131, 137-144, 146, and 147 are under consideration.

6. Because this action raises new grounds of rejection, it is made Non-Final.

Priority

7. Applicant's claim for priority under 35 U.S.C. 120 is acknowledged.

Information Disclosure Statement

8. The information disclosure statement (IDS) submitted on March 21, 2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Specification

9. **(New Objection)** The disclosure is objected to because of the following informalities: the Title is Missing from the first page of the specification.

Appropriate correction is required.

10. **(Prior Objection- Withdrawn)** The disclosure was objected as lacking a Brief Summary of the Drawings for Figures 9 or 10. Applicant's arguments are found persuasive. The objection is therefore withdrawn.

11. The amendments filed April 3 and May 5, 2006 are objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the material added after the paragraph ending on page .6 line 21, drawn from a declaration of Joseph E. Mueth. This Declaration was not part of the application as filed. It is not clear where support is found for this subject matter in the application as filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

12. **(Prior Objection- Withdrawn)** Claims 116-118 were objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 115. In view of the cancellation of these claims, the objection is withdrawn.

13. **(Prior Objection- Withdrawn)** Claim 112 was objected to because of the following informalities: the claim delineates the separate steps of the claim using numbers. In view of the cancellation of the claim, the objection is withdrawn.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. **(Prior Rejection- Restated)** Claims 112-114 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicant's arguments that those in the art would have understood what was meant by the phrase "at early times after infection" are found persuasive. However, the rejection is restated because it is not clear the effect that the language has on the claimed methods. It is not clear if the limitation is merely identifying a functional capability of the claimed method, or if some step is implied by the claim language. Neither the claims, nor the application teach that the language indicates that the language requires some additional step, or limits the application of the claimed method (e.g., to a specific subpopulation of individuals infected with, or at risk of infection with, HCV). Because it is not clear what is intended, the claims are read broadly such that the language indicates that the claimed method is capable of detecting HCV infection at early times after infection.

16. **(Prior Rejection- Withdrawn)** Claims 113-114 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which applicant regards as the invention. In view of the cancellation of these claims, the rejection is withdrawn.

17. **(New Rejection)** Claims 124-126, 129-131, 137-144, 146, and 147 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 124 and 129 are representative. Claim 124 reads on a method wherein an HCV antigen is admixed with a sample for form an "aqueous immunoreaction mixture." This language implies that the antigen is in soluble form in the implicit aqueous medium. However, claim 129 reads on "the method of claim 124" wherein the capsid antigen "is affixed to a solid matrix." Page 39 of the application indicates that the formation of an "aqueous immunoreaction mixture" would not include embodiments wherein the antigen is affixed to such a solid matrix. See e.g., page 39, second paragraph (stating that the "antigen is typically affixed to the solid matrix by adsorption *from* an aqueous medium"[emphasis added]). This is because, by teaching that the affixation results in adsorption of the antigen "from" the aqueous medium, the specification is indicating that such affixation is considered by the Applicant to remove the antigen from the aqueous medium. Thus, the two limitations do not appear to be compatible. It is therefore not clear what is the scope of the indicated claims.

For the purposes of this action, the claims are read as though they read on methods wherein the immunoreaction occurs within a aqueous medium, regardless as to whether the antigen is affixed to a solid support or not (i.e., if the sample is a fluid, the limitations of the claim are met).

It is further noted that there does not appear to be direct support for the claimed method of forming an "aqueous immunoreaction mixture" where the antigen is specifically required to not be affixed to a substrate in the application. If the Applicant amends the claims to focus more squarely on such embodiments, Applicant is also requested to point out where support for such embodiments may be found in the application as filed.

18. **(New Rejection)** Claim 131 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim reads on the method of claim 124, wherein the capsid antigen has the sequence from residues 21-40 CAP-B of SEQ ID NO: 73. It is not clear if the claim merely requires the presence of residues 21-40 of SEQ ID NO: 73, or requires the presence of the complete sequence of the CAP-B antigen as described on pages 20 and 25-26. For the purposes of this action, the broadest interpretation of the claim, reading on any antigen including residues 21-40, is applied.

The claim is also rejected because it is both unclear what effect the inclusion of the reference to CAP-N has on the antigen of subpart d of the claim. Moreover, it is noted that there does not appear to be a definition as to what a CAP-N antigen comprises in the application.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

20. **(New Rejection)** Claims 124-126, and 129-131 are rejected under 35 U.S.C. 102(e) as being anticipated by Houghton et al., (U.S. 5,350,671). These claims read on methods for the detection of HCV antibodies "at early times after infection" comprising forming an aqueous immunoreaction admixture by admixing a fluid sample with an HCV capsid antigen, allowing time for an immunoreaction to occur, and detecting the presence of the immunoreaction product. Claims 125 and 126 require the use of a labeled binding agent against the immunoreaction product, particularly where the binding agent is an anti-human IgG. Claim 129 requires that the antigen is affixed to a solid matrix. Claim 130 requires that the capsid antigen is in the form of a fusion protein. Claim 131 requires that the capsid antigen includes residues 21-40 of SEQ ID NO: 73.

Houghton teaches a method for the detection of anti-HCV antibodies comprising the providing an HCV peptide corresponding to residues 1-84, 9-177, or 1-120 of the sequence in Figure 20 of that reference (each of which includes the sequence of residues 21-40 of SEQ ID NO: 73); contacting the peptide with a biological sample (including fluid samples), and detecting the resulting immunocomplex (the immunoreaction product). See e.g., claims 9-12, and 29. The reference also teaches that the complexes may be detected through the use of labeled binding agents, including anti-immunoglobulin antibodies (claim 32) and demonstrates the use of a labeled goat anti-human IgG antibody (column 98). The reference teaches embodiments where

the immunoreaction occurs in an aqueous environment or where the antigen is affixed to a solid support. See e.g., Column 37, and claim 23. The reference also teaches that the antigenic peptides used in the disclosed methods may be in the form of fusion proteins. Columns 27-28. The reference therefore anticipates the indicated claims.

It is noted that the claims further recite that the claimed method is for the detection of anti-HCV antibodies early after infection. Because the reference teaches the same method as claimed, using the same HCV antigen, the method disclosed would inherently meet this functional limitation. This limitation therefore fails to distinguish over the prior art.

21. **(New Rejection)** Claims 124-126, 129, and 131 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang (U.S. 5,436,126). The claims have been described above. Wang teaches (and claims) a method for the detection of anti-HCV antibodies that comprises admixing a fluid sample with a HCV antigen comprising residues 21-40 of SEQ ID NO: 73, and detecting the resulting immunoreaction complexes, including methods wherein the antigen is affixed to a solid substrate. See e.g., claims 1, 2, 8, and 10. Further, claim 3 of the reference indicates that the immunoreaction product is detected through the use of an ELISA assay. The reference teaches the use of a labeled anti-human IgG antibody in the performance of this assay. See e.g., columns 30 and 31. Thus, the reference anticipates the indicated claims.

It is noted that this reference has the same priority date as the previously applied Wang reference. However, in the present instance, the reference is a patent claiming the same invention as the present claims. In such a case, a 131 declaration is not sufficient to overcome the rejection. See e.g., MPEP 715.05. Moreover, Applicant's arguments regarding the enablement for the invention provided in the patents are not found persuasive. Claimed subject matter in U.S.

Patents is presumed to be enabled. The present Examiner does not have the authority to conclude otherwise.

Further, as with the Houghton reference above, the method disclosed by the reference would inherently meet the functional limitation of the claims (i.e. the method would detect anti-HCV antibodies at early times after infection).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. **(Prior Rejection- Withdrawn)** Claims 112-114 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Wang et al. (U.S. 5,106,726) in view of the teachings of Houghton et al. (EP 0 318 218- of record in the March 2006 IDS). In view of Applicant's demonstration of prior conception and diligent pursuit of the claimed method in the Declaration of Torsten B. Helting (filed January 11, 2007), and the arguments submitted therewith in the Response of the same date, this rejection is withdrawn.

24. **(New Rejection)** Claims 124-126, 129-131, 138, 141, 143, 144, 146, and 147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton as applied to claims 124, 125, 126, 129, and 131 above. Claims 124-126 and 129-131 have been described above. As indicated above, the limitations of these claims are disclosed by the teachings of Houghton. The remaining

claims read on substantially the same methods, except that they require the presence of the additional HCV antigen known as C-100-3 in the antibody detection mixture. The Houghton reference does not specifically teach the combined use of the antigen described above in combination with the C-100-3 antigen. However, the reference does teach that the C100-3 polypeptide is also useful for the detection of anti-HCV antibodies in samples. See e.g., columns 75-76, 97-98, and 104-105. Because the reference teaches that this peptide would also be useful for the detection of anti-HCV antibodies, it would have been obvious to those of ordinary skill in the art to combine these antigens for the detection of anti-HCV antibodies. This is because it is prima facie obvious to combine compositions known in the art to perform the same function. See e.g., MPEP 2144.06. The teachings of the reference therefore render the claimed methods obvious.

25. **(New Rejection)** Claims 124-126, 129-131, 138, 141, 143, 144, 146, and 147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang as applied to claims 124-126, 129, and 131 above, further in view of Houghton et al., (U.S. 5,350,671). The claims have been described above. As indicated above, Wang anticipates the method of claims 124-126, 129, and 131. Wang does not however, specifically teach the use of a fusion protein comprising the indicated peptides, nor the combination of the C100-3 peptide with the core peptide for the detection of anti-HCV antibodies.

However, both the Wang and the Houghton references provide teaching relating the use of the C100-3 peptide as a useful peptide for detecting anti-HCV antibodies. See, Wang, column 3; and Houghton, columns 75-76, 97-98, 104-105. Because the reference teaches that this peptide

would also be useful for the detection of anti-HCV antibodies, it would have been obvious to those of ordinary skill in the art to combine these antigens for the detection of anti-HCV antibodies. This is because it is prima facie obvious to combine compositions known in the art to perform the same function. See e.g., MPEP 2144.06.

Further, as indicated above, the Houghton reference also teaches the use of fusion proteins comprising the target antigens for the detection of anti-HCV antibodies. See e.g., columns 27-28. Because the Houghton reference provides teachings relating to the use of HCV peptides for the detection of anti-HCV antibodies, it would have been apparent to those of ordinary skill in the art to apply these teachings to the use of the peptides of Wang, which are disclosed as being used in the same type of methods. Because the peptides of both references are disclosed as useful for the same purposes, and in the same methods, those of ordinary skill in the art would have had a reasonable expectation of success in the combination.

The combined teachings of these references therefore render the claimed methods obvious.

Double Patenting

26. **(New Warning)** Applicant is advised that should claim 140 and 142 be found allowable, claim 137 and 139 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

27. No claims are allowed.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Z. Lucas
Patent Examiner